Complete Summary

GUIDELINE TITLE

Practice parameters for ambulatory anorectal surgery.

BIBLIOGRAPHIC SOURCE(S)

Place R, Hyman N, Simmang C, Cataldo P, Church J, Cohen J, Denstman F, Kilkenny J, Nogueras J, Orsay C, Otchy D, Rakinic J, Tjandra J. Practice parameters for ambulatory anorectal surgery. Dis Colon Rectum 2003 May; 46(5):573-6. [47 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Society of Colon and Rectal Surgeons. Practice parameters for ambulatory anorectal surgery. Arlington Heights (IL): American Society of Colon and Rectal Surgeons; 1998-1999. 3 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web site</u> for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning,

highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the <u>FDA Web</u> site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

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SCOPE

DISEASE/CONDITION(S)

Anorectal conditions for which ambulatory anorectal surgery may be indicated, including condylomata, fissures, abscesses, fistulas, tumors, hemorrhoids, pilonidal disease, and various miscellaneous conditions

GUIDELINE CATEGORY

Evaluation Management Treatment

CLINICAL SPECIALTY

Colon and Rectal Surgery Surgery

INTENDED USERS

Health Care Providers
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Utilization Management

GUI DELI NE OBJECTI VE(S)

To provide appropriate recommendations for ambulatory anorectal surgery

TARGET POPULATION

Patients requiring ambulatory anorectal surgery

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

- 1. Selection of patients for ambulatory anorectal surgery
- 2. Patient history
- 3. Physical examination
- 4. Preoperative investigations (e.g., lab studies, electrocardiograms) (not recommended routinely)

Intraoperative and Postoperative Management of Anorectal Surgery

- 1. Use of local anesthetics
- 2. Use of Aldrete score to determine phase 1 and phase 2 recovery
- 3. Post-Anesthetic Discharge Scoring System
- 4. Postoperative pain control
 - Oral narcotics
 - Toradol® (intramuscular or intravenous)
 - Sulindac suppositories
 - Metronidazole (oral)
- 5. Limitation of perioperative fluid
- 6. Post-operative education
 - Sitz bath
 - Fluid intake
 - Activity limitations

MAJOR OUTCOMES CONSIDERED

- Need for hospital admission
- Rate of perioperative complications
- Predictive value of laboratory screening tests
- Incidence of urinary retention
- Patient comfort and satisfaction
- Cost

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level I

Evidence from properly conducted randomized, controlled trials

Level II

Evidence from controlled trials without randomization, or cohort or case-control studies, or multiple times series, dramatic uncontrolled experiments

LevelIII

Descriptive case series or opinions of expert panels

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Review of published cost analyses showed a reduction in hospital charges of 25 to 50 percent when anorectal surgery is performed on an outpatient basis.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The Levels of Evidence (I–III) are defined at the end of the "Major Recommendations" field.

Ambulatory Facilities

Anorectal Surgery May Be Safely and Cost-Effectively Performed in an Ambulatory Surgery Center.

Level of evidence - Class III. It has been estimated that 90 percent of anorectal cases may be suitable for ambulatory surgery. A wide variety of anorectal conditions including condylomata, fissures, abscesses, fistulas, tumors, hemorrhoids, pilonidal disease, and various miscellaneous conditions have been shown to be amenable to surgery on an outpatient basis. An admission rate of 2 percent has been reported. A reduction in hospital charges of 25 to 50 percent has also been noted.

Patients With American Society of Anesthesiology (ASA) Classifications I and II Are Generally Considered Suitable Candidates for Outpatient Anorectal Surgery (refer to Appendix B in the original guideline document).

Level of evidence - Class III. Multiple factors must be considered in determining the appropriateness of performing anorectal surgery in the ambulatory setting. The ASA physical status classification is useful to determine the risk of anesthesia. The magnitude of the proposed surgery, type of anesthesia, availability of appropriate instrumentation, ability of the patient to follow instructions, distance of the patient's home from the surgical center, and home support structure all need to be considered.

Selected ASA Category III Patients May Also Be Appropriate Candidates.

Preoperative Evaluation

Preoperative Investigations (e.g., Laboratory Studies and Electrocardiograms) Should Be Dictated by History and Physical Examination.

Level of evidence - Class III. Multiple studies have documented that patient history and physical examination are the key elements of an appropriate preoperative evaluation. Routine preoperative investigations that are not warranted on the basis of history and physical seem to provide little further information. There is clear evidence that nonselective preoperative screening yields few abnormal results.

Intraoperative Considerations

Most Anorectal Surgery May Be Safely and Cost-Effectively Performed Under Local Anesthesia; Regional or General Anesthesia May Be Used Depending Upon Patient or Physician Preference.

Level of evidence - III. The use of local anesthetics such as monitored anesthetic care for anorectal surgery is safer and has fewer complications than other anesthetic techniques. Perianal infiltration of local anesthetics is a simple procedure that is easily learned. Injection of the local anesthetics can be accomplished in less than five minutes and the operation begun immediately. However, the anesthetic technique used for any procedure should be the one that provides for maximal safety and efficacy.

Postoperative Considerations

Anorectal Surgery Patients May Safely Be Discharged From the Postanesthesia Care Unit.

Level of evidence - II. The time course for recovery from anesthesia includes early recovery, intermediate recovery, and late recovery. Early recovery is the time interval for anesthesia emergence and recovery of protective reflexes and motor activity. The Aldrete score has been used for 30 years to determine release from phase 1 (early) recovery to a hospital bed or phase 2 (intermediate) recovery. Intermediate recovery is the period during which coordination and physiology normalize to an extent that the patient can be discharged from phase 2 recovery in a state of "home readiness" and be able to return home in the care of a responsible adult. The Post-Anesthetic Discharge Scoring System has been shown to be efficacious for discharge.

Multiple Modalities May Be Used to Achieve Adequate Postoperative Pain Control. Level of evidence - II. If local anesthetics are not used as the primary anesthetic technique, their use will provide prolonged postoperative analgesia. Oral narcotics may be used as primary postoperative analgesia. The use of nonsteroidal anti-inflammatory drugs, particularly intramuscular or intravenous Toradol® (Roche Pharmaceuticals, Nutley, NJ) or sulindac suppositories, has also shown improved analgesia, lower narcotic usage, and lower rates of urinary retention. Although the effect is unknown, oral metronidazole shows improved postoperative pain control.

Postoperative Urinary Retention Can Be Reduced by Limiting Perioperative Fluid Intake.

Level of evidence - III. Multiple studies have shown that limiting perioperative fluid lowers the incidence of postoperative urinary retention. These same studies show conflicting evidence over the relationship between gender, age, and the quantity of narcotic medication and urinary retention. Hemorrhoidectomy and the performance of multiple anorectal procedures have higher rates of urinary retention.

Postoperative Education Should Include Recommendations for Sitz Baths, Fluid Intake, and Activity Limitations.

Level of evidence - III. Textbooks of anorectal surgery advocate consistent instructions before discharge from ambulatory surgery. Although derived from common sense, scientific justification does not exist. With appropriate

communication, ambulatory anorectal surgery may be performed with a high degree of patient satisfaction.

Definitions:

Levels of Evidence

Level I

Evidence from properly conducted randomized, controlled trials

Level II

Evidence from controlled trials without randomization, or cohort or case-control studies, or multiple times series, dramatic uncontrolled experiments

LevelIII

Descriptive case series or opinions of expert panels

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate utilization of ambulatory anorectal surgery
- Potential benefits of outpatient surgery include more rapid return to the comforts of a home environment, diminished opportunities for nosocomial complications, and diminished cost.
- With appropriate communication, ambulatory anorectal surgery may be performed with a high degree of patient satisfaction.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are inclusive and not prescriptive. Their purpose is to provide information on which decisions can be made, rather than dictate a specific form of treatment.
- The practice parameters set forth in this document have been developed from sources believed to be reliable. The American Society of Colon and Rectal Surgeons makes no warranty, guarantee, or representation whatsoever as to the absolute validity or sufficiency of any parameter included in this document, and the Society assumes no responsibility for the use or misuse of the material contained here.
- It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all of the circumstances presented by the individual patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 May

GUI DELI NE DEVELOPER(S)

American Society of Colon and Rectal Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Colon and Rectal Surgeons

GUI DELI NE COMMITTEE

The Standards Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Drs. Ronald Place; Neal Hyman (Project Coordinators); Clifford Simmang (Committee Chairman); Peter Cataldo; James Church; Jeff Cohen; Frederick Denstman; John Kilkenny; Juan Nogueras; Charles Orsay; Daniel Otchy; Jan Rakinic; Joe Tjandra

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Society of Colon and Rectal Surgeons Web site</u>.

Print copies: Available from the American Society of Colon and Rectal Surgeons, 85 W. Algonquin Rd., Suite 550, Arlington Heights, IL 60005

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on October 8, 2004. The information was verified by the guideline developer on October 25, 2004. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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